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10/723,323

11/26/2003

Enrico Alessi

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EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/723,323

Applicant(s)

ALESSI ET AL.

Examiner

Jerry Lin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 13-17 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2007 has been entered.

### ***Status of the Claims***

Claims 1, 3-8 and 13 -17 are under examination.

Claims 9-12 are withdrawn as being drawn to an unelected invention.

Claim 2 is cancelled.

### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities: In the second to last line of claim 1, the claim recites "...values greater that the threshold...." The phrase should be amended to read "... values greater than the threshold..." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-8, and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "likely" in claims 1, 13, 15-17 is a relative term which renders the claim indefinite. The term "likely" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 5 recites the limitation "the combination" and "the final value" and "the respective value" in lines 7-10. There is insufficient antecedent basis for this limitation in the claim. This limitation was not mentioned previously in the instant claim or in any of the claims from which the instant claim depends.

Claim 5 recites the limitations "the values of gene expression" in line 11. There is insufficient antecedent basis for these limitations in the claim. These limitations was not mentioned previously in the instant claim or in any of the claims from which the instant claim depends.

Claim 8 recites the limitation "the interval" in line 3. There is insufficient antecedent basis for this limitation in the claim. This limitation was not mentioned previously in the instant claim or in any of the claims from which the instant claim depends.

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Claim 8 recites in line 2, "the combination." However, in the claims from which claim 8 depends, multiple combinations are established. It is unclear to which of these previously established combinations is the instant limitation referring.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-7, and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Getz et al. (PNAS (2000) Volume 97, Number 22, pages 12079-12084) in view of Dougherty et al. (Journal of Computational Biology (January 2002) Volume 9, Number 1, pages 105-126) further in view of Tolley (US 2004/0128080).

The instant claims are drawn to a method of clustering wherein a dataset is clustered into smaller datasets, the smaller datasets are paired and subjected to filtering, characteristic parameters of the pairs are calculated, a value is generated as a function of the parameters, and pairs with values greater than a threshold are identified as network of genes and pairs with values lower than a threshold are discarded.

Regarding claims 1, 13, and 15-17, Getz et al. teach a method of clustering wherein a dataset is clustered (page 12080, left column); where groups of genes satisfy a clustering criterion (page 12080, left column); establishing all possible pairs of sub-tables (clusters) (page 12080, left column); applying a logic filtering criterion (defined in the specification as any logic criterion that a user may impose on the data (See specification, page 8, paragraph 50), i.e. selecting only those genes whose minimal expression over all samples is greater than 20) (page 12081, right column); calculating the parameters of the data in each pair combination (page 12080, left column); and identifying pair combinations whose values is greater than a threshold as a network of genes and discarding combination genes whose values are smaller than a threshold (abstract; page 12080- page 12081, left column, top).

However, Getz et al. do not disclose using a decision algorithm based on soft computing or wherein the datasets are presented in tables.

Regarding claims 1, 13, and 15-17, Tolley teaches using clustering algorithms on datasets that are presented in tables (page 7, paragraph 0059-0062; page 11, paragraph 0096) and outputting the results to a user selected format (page 7, paragraph 0054).

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Regarding claims 1, 3, 13, and 15-17, Dougherty et al. teach that data may be clustered using a variety of soft computing techniques including fuzzy logic (abstract).

Regarding claim 4, Getz et al. also teach that the parameter is tied to gene expression levels (page 12082, left column).

Regarding claim 5, Tolley also teaches that the parameter is a correlation coefficient (page 1, paragraph 004).

Regarding claim 6, Getz et al. also teach that clusters with a low number of genes are eliminated (eliminating clusters that do not satisfy a size criteria) (page 12080, left column).

Regarding claim 7, Dougherty et al. disclose using SOM or K-means clustering (page 1118).

Regarding claim 14, Dougherty et al. teach training the fuzzy logic not using any online capabilities (page 124).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of Getz et al., Dougherty et al. and Tolley to incorporate the benefits of fuzzy logic in the method of Getz et al. Getz et al. states that their goal is to create a more accurate clustering method (abstract). Getz et al. attempt to create a more accurate clustering method by utilizing a two-way clustering approach (abstract). Dougherty et al. is also concerned with improving the accuracy of clustering algorithms (abstract). In order to determine the best clustering algorithms, Dougherty et al. compares several known techniques. They find that Fuzzy logic as one of the means that has more accuracy than other means (page 118-page 120, top). Thus, one

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of ordinary skill in the art seeking to improve the accuracy of clustering algorithms would have been motivated to combine the methods of Dougherty et al. and Getz et al., since each method improves different components of a clustering algorithm. Furthermore, Tolley teaches that databases are typically organized in tables (page 7, paragraph 0057). Thus, one of ordinary skill in the art would expect to perform the method of Dougherty et al. and Getz et al. on a database organized in tables.

### ***Withdrawn Rejections***

7. Applicant's arguments, see Remarks, filed June 25, 2007, with respect to the rejection(s) of claim(s) 1, 3-7, 13 and 14 under 35 U.S.C. §103(a) as being unpatentable over Shamir et al. in view of Dougherty et al. further in view of Tolley have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendments.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Majorie A. Moran can be reached at (571) 272-0720. The fax phone



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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.  
PRIMARY EXAMINER